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DEC 2 2 2005

510(k) Summary
for the Life-Shield Products, Inc.
CAREO Safety Syringe
(per 21CFR807.92)

1. SPONSOR

Life-Shield Products, Inc.
3F, No. 10, Wuchiuan 7th Rd
Wugu Industrial Park
Taipei, Taiwan 248
ROC

Contact Person: Mr. Kurt Lo, Vice President
Telephone: 011-866-2-2299-6033

Date Prepared: May 30, 2005

2. DEVICE NAME

Proprietary Name:	CAREO Safety Syringe
Common/Usual Name:	Hypodermic Syringe (with needle)
Classification Name:	Piston syringe
	Hypodermic single lumen needle

3. PREDICATE DEVICE

- SafePro* Safety Syringe (K012726)
- SECUREGARD® Retractable Safety Syringe (K012121)
- CAREO Retractable Safety Syringe (K030976)

4. DEVICE DESCRIPTION

The Life-Shield Products, Inc., CAREO Safety Syringe is a sterile, single use and disposable, 3, 5, 10 mL piston syringe, provided with a permanently attached needle in twelve product configurations. The CAREO Safety Syringe is similar in appearance, size, materials, operation, and purpose to the cited predicate device and other conventional single use, sterile, disposable syringes.

5. INTENDED USE

The CAREO Safety Syringe is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient. The syringe should not be used for blood collection.

The CAREO Safety Syringe aids in the prevention of needlestick injuries. In addition, when the user breaks the plunger, the CAREO Safety Syringe reduces the possibility of syringe reuse.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Life-Shield Products, Inc., makes a claim of substantial equivalence of the CAREO Safety Syringe to the SafePro* Safety Syringe (K012726), SECUREGARD® Retractable Safety Syringe (K012121) and CAREO Retractable Safety Syringe (K030976) based on similarities in intended use, design, technological and operational characteristics. All three are indicated for injecting fluids into the body, while helping to reduce the risk of sharps injuries. All syringes are piston syringes that use permanently attached single lumen hypodermic needles. All syringes are provided sterile, single-use, and disposable. All syringes require the user to manually retract the needle-plunger into the syringe barrel, break off the plunger rod, and discard the pieces.

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7. TESTING

Testing provided in this premarket notification includes physiochemical compatibility, biocompatibility, and standard conformity. Side-by-side comparison of CAREO Safety Syringe, SafePro* Safety Syringe, SECUREGARD® Retractable Safety Syringe and the CAREO Retractable Safety Syringe shows that three products are equivalent. Simulated use testing has demonstrated that the CAREO Safety Syringe performs according to specification. Testing also supports the claimed Indications for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Dr. Jen, Ke-Min
Consultant
Life-Shield Products, Incorporated
3F, No.10, Wuchiuan 7th Road
Wugu Industrial Park
Taipei, 248, Taiwan

Re: K052397
Trade/Device Name: CAREO Safety Syringe (3cc/mL, 5cc/mL, 10cc/mL)
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: December 2, 2005
Received: December 8, 2005

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: **LIFE-SHIELD Products, Inc.**
CAREO Safety Syringe (3cc/mL, 5cc/mL, 10cc/mL)

INTENDED USE

The CAREO Safety Syringe is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for intramuscular and subcutaneous injection of medication into a patient. The syringe should not be used for blood collection.

The CAREO Safety Syringe aids in the prevention of needlestick injuries. In additional, when the user breaks the plunger, the CAREO Safety Syringe reduces the possibility of syringe reuse.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila N. Murphy for DMCB/DGHD 12/22/05

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